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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,189	03/18/2002	Charles Lavigne	28.018	4897

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EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/018,189	Applicant(s) LAVIGNE ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,13,16,19-21,26,29,30,41,45,48,50,65,68 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-5,7-12,14,15,17,18,22-25,27,28,31-40,42-44,46,47,49,51-64,66,67,69 and 71.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II in Paper No. 7 is acknowledged. Claims 1 – 5, 7 – 12, 14, 15, 17, 18, 22 – 25, 27, 28, 31 – 40, 42 – 44, 46, 47, 49, 51 – 64, 66, 67, 69 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 13, 16, 19 – 21, 26, 29, 30, 41, 45, 48, 50, 65, 68 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 provides for the use of a fish protein, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 6 is rendered vague and indefinite for reciting "normal insulin function" because this phrase is not adequately defined by the claim language or specification.

Claim 13 and its dependents are rendered vague and indefinite for reciting both "preventing" and "animal suffering therefrom" because it is unclear how a method of preventing applies to an animal already suffering from insulin resistance.

Claim 16 and its dependents are rendered vague and indefinite because it appears to omit essential steps to the method. For example, is the method accomplished by simply consuming one or more of the compounds?

In claims 19 and 29, line 2, "hyperglycemia" lacks sufficient antecedent basis.

Claims 20, 45, 48 and 50 are rendered vague and indefinite because it is unclear how "cod fish" is a fish protein. Applicant may prefer to include the term "from" between "is" and "cod" to more clearly claim the invention.

Claim 26 and its dependents are rendered vague and indefinite for reciting both "preventing" and "animal suffering therefrom" because it is unclear how a method of preventing applies to an animal already suffering from insulin resistance.

Claim 26 is further indefinite for including parenthesis because it is unclear if the feature introduced by the parenthesis is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims.

Claim 26 is confusing for reciting "a mixture of one or more" because it is unclear how one can have a mixture of a single compound.

Claim 26 is further confusing because it is unclear what proportions of amino acids are required to meet the claim. It is unclear what amount of amino acid the recited number represents.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 26, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Gohman et al (US 6143786 A).

Applicant claims a method for preventing/treating insulin resistance in a human or non-human animal comprising administering an effective amount of one or more of specified amounts of alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, lysine, phenylalanine, proline, serine, threonine, tyrosine and valine. The insulin

resistance is from Type 1 or 2 diabetes and the compounds are combined with a carries, adjuvant, or vehicle.

Goham teaches a method for treating insulin resistance, the method comprising administering an effective amount of L-arginine to a person with Type II diabetes, in combination with a meal (abstract, examples).

The reference anticipates the claimed subject matter.

6. Claims 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiner et al (US 5843886 A).

Applicant claims a method for preventing/treating insulin resistance in a human or non-human animal comprising administering an effective amount of one or more of specified amounts of alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, lysine, phenylalanine, proline, serine, threonine, tyrosine and valine. The insulin resistance is from Type 1 or 2 diabetes and the compounds are combined with a carries, adjuvant, or vehicle.

Weiner teaches methods for preventing or treating Type I diabetes (or insulin resistance) the method comprising administering insulin fragments (col.4 line 48-52) wherein the fragments are peptides or polypeptides with amino acid sequences of insulin (col.5 line 29-59). The composition may further contain carriers (col.6 line 63-67).

Since amino acid sequences of insulin contain some or all of the above amino acids, the reference anticipates the claimed subject matter.

7. Claims 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (US 5830434 A).

Applicant claims a method for preventing/treating insulin resistance in a human or non-human animal comprising administering an effective amount of one or more of specified amounts of alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, lysine, phenylalanine, proline, serine, threonine, tyrosine and valine. The insulin resistance is from Type 1 or 2 diabetes and the compounds are combined with a carries, adjuvant, or vehicle.

Taylor teaches methods for treating Type II diabetes (or insulin resistance), the method comprising administering polypeptides (col.1 line 50-54) of the sequences containing the claimed amino acids (col.3 line 30-37) and carriers (claims).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 6, 13, 16, 19 – 21, 26, 29, 30, 41, 45, 48, 50, 65, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takasaki et al. (US 4584197).

Applicant claims a method for restoring normal insulin function in an insulin resistant mammal, comprising administering one or more of fish protein, hydrolyzed fish protein, or fish protein amino acids. Applicant additionally claims a method for preventing/treating insulin resistance in a human or non-human animal, the method comprising administering an effective amount of one or more of fish protein, hydrolyzed fish protein or fish protein amino acids. Applicant claims a method for treating insulin resistance in a human or non-human animal, comprising administering a diet comprising 4 – 60% of one or more of fish protein, hydrolyzed fish protein or fish protein amino acids. The insulin resistance is the result of Type 1 or 2 diabetes, the fish protein is from cod fish and the compounds are combined with a carrier, adjuvant or vehicle. Finally, Applicant claims a method for preventing/treating insulin resistance in a human or non-human animal comprising administering an effective amount of one or more of specified amounts of alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, lysine, phenylalanine, proline, serine, threonine, tyrosine and valine. The insulin resistance is from Type 1 or 2 diabetes, the compounds are combined with a carries, adjuvant, or vehicle and fish protein is from cod fish.

Takasaki teaches compositions comprising fish extracts which comprise peptide amino acids with insulin-like function for relieving diabetes (or insulin resistance) (abstract). Specifically, the fish extracts are from cod fish (col.3 line 62-65) and the amino acids include arginine, lysine, tyrosine, leucine, isoleucine, valine, methionine, alanine, glycine, proline, glutamic acid, serine, threonine, aspartic acid, arginine, phenylalanine and histidine (Table 1). The composition further comprises carriers (examples, claims).

Takasaki does not specifically teach a method for preventing or treating insulin resistance. However, Takasaki does teach that the composition has insulin like properties and may be used to treat diabetes (example 4). At the time of the claimed invention, it was well known in the art that insulin resistance is a function of diabetes. As such, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Takasaki to use the composition for its disclosed (and claimed) use with a reasonable expectation for successfully treating and/or preventing insulin resistance.

11. Claims 6, 13, 16, 19 – 21, 26, 29, 30, 41, 45, 48, 50, 65, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gohman, Weiner or Taylor in view of Takasaki.

Applicant claims a method for restoring normal insulin function in an insulin resistant mammal, comprising administering one or more of fish protein, hydrolyzed fish protein, or fish protein amino acids. Applicant additionally claims a method for preventing/treating insulin resistance in a human or non-human animal, the method comprising administering an effective amount of one or more of fish protein, hydrolyzed fish protein or fish protein amino acids. Applicant claims a method for treating insulin resistance in a human or non-human animal,

comprising administering a diet comprising 4 – 60% of one or more of fish protein, hydrolyzed fish protein or fish protein amino acids. The insulin resistance is the result of Type 1 or 2 diabetes, the fish protein is from cod fish and the compounds are combined with a carrier, adjuvant or vehicle. Finally, Applicant claims a method for preventing/treating insulin resistance in a human or non-human animal comprising administering an effective amount of one or more of specified amounts of alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, methionine, lysine, phenylalanine, proline, serine, threonine, tyrosine and valine. The insulin resistance is from Type 1 or 2 diabetes, the compounds are combined with a carries, adjuvant, or vehicle and fish protein is from cod fish.

Goham teaches a method for treating insulin resistance, the method comprising administering an effective amount of L-arginine to a person with Type II diabetes, in combination with a meal (abstract, examples).

Weiner teaches methods for preventing or treating Type I diabetes (or insulin resistance) the method comprising administering insulin fragments (col.4 line 48-52) wherein the fragments are peptides or polypeptides with amino acid sequences of insulin (col.5 line 29-59). The composition may further contain carriers (col.6 line 63-67). Since amino acid sequences of insulin contain some or all of the above amino acids, the reference anticipates the claimed subject matter.

Taylor teaches methods for treating Type II diabetes (or insulin resistance), the method comprising administering polypeptides (col.1 line 50-54) of the sequences containing the claimed amino acids (col.3 line 30-37) and carriers (claims).

The references do not teach the methods wherein the peptides (proteins) are from cod fish. However, Takasaki teaches compositions comprising cod fish extracts which comprise peptide amino acids with insulin-like function for relieving diabetes (or insulin resistance) (abstract, col.3 line 62-65) and wherein the amino acids include arginine, lysine, tyrosine, leucine, isoleucine, valine, methionine, alanine, glycine, proline, glutamic acid, serine, threonine, aspartic acid, arginine, phenylalanine and histidine (Table 1). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Takasaki to use fish proteins in the methods of Goham, Weiner and/or Taylor, for its disclosed insulin like function, with a reasonable expectation for successfully treating and/or preventing insulin resistance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
September 16, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER